4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0413]

Baxter Healthcare Corporation, et al.; Withdrawal of Approval of 14 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, Health and Human Service (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 14 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 075695	Butorphanol Tartrate Injection, 1 milligram (mg)/milliliter (mL), and 2 mg/mL	Baxter Healthcare Corporation, One Baxter Pkwy., Deerfield, IL 60015

Application No.	Drug	Applicant
ANDA 075697	Butorphanol Tartrate Injection, 2 mg/mL	Do.
ANDA 077290	Oxycodone Hydrochloride (HCl) Tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg	Nesher Pharmaceuticals (USA) LLC, 13910 St. Charles Rock Rd., Bridgeton, MO 63044
ANDA 078564	Granisetron HCl Injection, Equivalent to (EQ) 1 mg base/mL (EQ 1 mg base/mL)	Morton Grove Pharmaceuticals Inc., 6451 Main St., Morton Grove, IL 60053
ANDA 078565	Granisetron HCl Injection, EQ 4 mg base/4 mL (EQ 1 mg base/mL)	Do.
ANDA 078566	Granisetron HCl Injection, EQ 0.1 mg base/mL (EQ 0.1 mg base/mL)	Do.
ANDA 088342	Fluoxymesterone Tablets, 10 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369
ANDA 202032	Lamivudine Tablets, 150 mg and 300 mg	Aurobindo Pharma USA, Inc., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520
ANDA 205322	Efavirenz Tablets, 600 mg	Do.
ANDA 205690	Choline C-11 Injection, 4-100 millicurie/mL	University of Texas MD Anderson Cancer Center, 1881 East Rd., Unit 1903, Houston, TX 77054
ANDA 207653	Rosuvastatin Calcium Tablets, EQ 5 mg base, EQ 10 mg base, EQ 20 mg base, EQ 40 mg base	SciRegs International, Inc., 6333 Summercrest Dr., Columbia, MD 21045
ANDA 208199	Azelastine HCl Metered Spray, 0.2055 mg/spray	Amneal Pharmaceuticals LLC, 50 Horseblock Rd., Brookhaven, NY 11719
ANDA 210032	Azelastine HCl Metered Spray, 0.2055 mg/spray	Akorn Operating Company LLC, 1925 West Field Ct., Suite 300, Lake Forest, IL 60045
ANDA 211461	Bosentan Tablets, 62.5 mg and 125 mg	Syneos Health Global Headquarters, 1030 Sync St., Third Floor, Morrisville, NC 27560

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table.

Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: April 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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